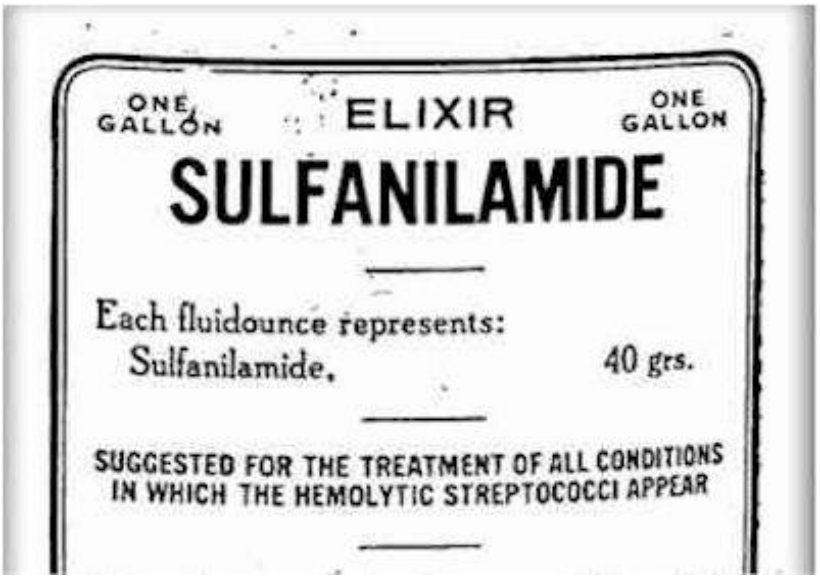
The Story Behind enactment of the FFDCA
(courtesy of info@knowledgenews.net)



240 Gallons of Poison
In the mid-1930s, doctors enthusiastically prescribed a new kind of drug to combat dangerous bacterial infections: sulfa drugs. These drugs inhibited bacteria from reproducing and, in the decade before penicillin became widespread, saved countless lives. In fact, doctors still use sulfa drugs today.

In 1937, a salesman for the S.E. Massengill Co. told his bosses that doctors were asking for a liquid sulfa drug that they could give to children. So the company's chief chemist combined the medicine with a solvent called diethylene glycol (DEG) and spiked it with raspberry extract. The company tested the medicine to make sure that its taste and smell were appealing. Nobody tested it for toxicity.

Diethylene glycol is a lethal liquid used today in antifreeze and industrial solvents. Massengill used it to produce 240 gallons of "Elixir Sulfanilamide" and shipped one-gallon jugs across the country. Just a few weeks later, the American Medical Association (AMA) received the first reports of deaths linked to the medicine. Bewildered families said the victims experienced severe abdominal pain, vomiting, and convulsions. Death came after several weeks.

The FDA Steps In
The Massengill company sent telegrams to pharmacies, requesting the return of the product, but neglected to mention that the elixir was killing people. It fell on the AMA to publicize the danger by alerting radio stations and newspapers and on the FDA to confiscate the elixir.

FDA commissioner Walter Campbell mobilized practically everyone who worked for the agency. FDA agents sifted through more than 20,000 shipping orders to find out where the elixir was and located hundreds of Massengill salesmen to learn which doctors were

given free samples. More than 200 FDA employees went out to talk to doctors and druggists. One by one, they tracked down who prescribed the toxic medicine and the people who took it home.

A few doctors refused to admit they had prescribed the medicine and tried to cover up their patients' deaths. But others were in agony. "Nobody but Almighty God and I can know what I have been through these past few days," wrote Dr. Archie Calhoun of Mississippi. "Six human beings, all of them my patients, one of them my best friend, are dead because they took medicine that I prescribed for them."

More Than 100 Victims

Of the 240 gallons that were distributed, the FDA rounded up more than 234. Of the 353 people who took the drug, 34 children and 71 adults died. The final death in the debacle was of the chemist who formulated the drug for Massengill. He died of a self-inflicted gunshot wound.

Congress reacted to the crisis by passing the 1938 Food, Drug, and Cosmetic Act. The law, which has been modified over the years, compels a drug company to collect particular kinds of data--like toxicity results--before it can ask the FDA for permission to even test new drugs on humans. Now, tainted imports have Americans debating whether to impose similar controls on other consumer goods as well.